In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: October 27, 2022

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| MARY ELLOUISE BOND, | * | No. 16-1615V |
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| Petitioner, | * | Special Master Sanders |
| v. | * | - |
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| SECRETARY OF HEALTH | * | Dismissal; Insufficient Proof; Human |
| AND HUMAN SERVICES, | * | Papillomavirus ("HPV" or "Gardasil") |
| | * | Vaccine; Premature Ovarian Failure/ |
| Respondent. | * | Primary Ovarian Insufficiency ("POF/POI") |
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Mark T. Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner. Dorian Hurley, U.S. Department of Justice, Washington, DC, for Respondent.

DISMISSAL DECISION¹

On December 6, 2016, Mary Ellouise Bond ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program² ("Vaccine Program" or "Program"). 42 U.S.C. § 300aa-10 to 34 (2012). Pet. at 1, ECF No. 1. The petition alleges that the human papillomavirus ("HPV" or "Gardasil") vaccinations Petitioner received on February 15, 2013, April 23, 2013, and September 27, 2013, caused her to suffer from premature ovarian failure ("POF"), early onset menopause, and sterilization. *Id.* The information in the record, however, does not show entitlement to an award under the Program.

On March 2, 2017, Respondent filed his Rule 4(c) report. Resp't's Report, ECF No. 11. Respondent argued that Petitioner had not satisfied her burden of proof under *Althen*, as "[t]here is nothing in the record offering a medical theory causally connecting the HPV vaccine to [P]etitioner's injury and none of her treating doctors attributed her condition to the vaccine." *Id.* at 4. Following the submission of several rounds of expert reports, this case was consolidated with

¹ This Decision shall be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet**. In accordance with Vaccine Rule 18(b), a party has 14 days to identify and move to delete medical or other information that satisfies the criteria in § 300aa-12(d)(4)(B). Further, consistent with the rule requirement, a motion for redaction must include a proposed redacted decision. If, upon review, the I agree that the identified material fits within the requirements of that provision, such material will be deleted from public access.

² National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755 ("the Vaccine Act" or "Act"). Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

several other POI matters to determine if any of the cases could proceed in light of the causation theory proposed in each of the petitioners' cases. *See*, *e.g.*, ECF Nos. 23, 33–38, 42, 45, 53, 62–63. On December 6, 2019, I held a status conference with the parties to discuss the presentation of the parties' arguments with respect to the viability of a causation theory pursuant to *Althen* prong one. *See* Min. Entry, docketed Dec. 6, 2019; *see also* No. 15-183V, ECF No. 80. Petitioner filed her brief on *Althen* prong one on June 18, 2020. No. 15-183V, ECF No. 86. Respondent submitted a response on September 22, 2020, and Petitioner filed a reply on November 20, 2020. No. 15-183V, ECF Nos. 88, 90.

I issued a ruling on *Althen* prong one on August 30, 2021, finding that the petitioners in the consolidated POI cases have presented a causation theory that, while not applicable to all of them, does survive *Althen* prong one under limited, specific circumstances. *See* Findings of Fact at 24, ECF No. 68. On December 14, 2021, I held a status conference in this matter to discuss whether preponderant evidence has been submitted showing that Petitioner suffers from POI with an autoimmune etiology so that she may proceed under *Althen* prongs two and three. Sched. Order at 1, ECF No. 70. Petitioner requested sixty days to file updated medical records, including antibody test results, and a status report indicating whether this case will proceed or be dismissed, and I granted her request. *See id*.

Petitioner filed an unopposed motion for an extension of time to file the requested information on February 14, 2022. ECF No. 71. I stayed Petitioner's motion and ordered her to file a status report indicating whether the case will proceed with expert reports; and/or an explicit motion to supplement Petitioner's request for more time to file medical records containing additional objective testing. ECF No. 72. On March 15, 2022, Petitioner filed a supplemental motion for an extension of time alleging that she had normal antibody results in January of 2022, but she wished to consult an endocrinologist to determine if there was another way to establish an autoimmune etiology for her injury. ECF No. 73. Respondent noted that he did not see the relevance of such testing when it was performed six years after the onset of Petitioner's symptoms, and she previously yielded negative antibody results. *Id.* at 2.

I held a status conference with the parties on April 12, 2022, to discuss the ongoing issues related to establishing an autoimmune etiology for Petitioner's injury. Min. Entry, docketed Apr. 12, 2022. Petitioner again requested sixty days to file a status report identifying evidence regarding her basis to proceed with *Althen* prongs two and three consistent with the factors outlined in my ruling on *Althen* prong one. *See* ECF No. 74. I denied Petitioner's motion as moot and ordered her to file updated medical records containing antibody testing, if applicable, and a status report indicating that the case will not proceed or outlining the evidence she is relying on to continue with her claim. *See id.* I specifically told Petitioner to address the factors enumerated in my ruling on *Althen* prong one, aside from any recent positive antibody results if there have been years between such results and the onset of Petitioner's symptoms, and/or prior negative results. *Id.*

Following one extension of time, Petitioner filed a status report indicating she planned to rely on her abnormal thyroid function, a finding of small ovaries, and a notation that her POI could be autoimmune to proceed on *Althen* prongs two and three. ECF No. 77 at 1–2 (citing Pet'r's Ex. 2 at 19, 22, ECF No. 1-3; Pet'r's Ex. 4 at 2, ECF No. 1-5). I cautioned Petitioner that without more, Petitioner will likely be unsuccessful in establishing the applicability of the proposed biological

mechanism and ordered her to file an expert report in support of her claim. ECF No. 78. Petitioner did not file an expert report on prongs two and three. *See, e.g.*, ECF Nos. 79, 81–83. Accordingly, Respondent filed a motion to dismiss on October 12, 2022. ECF No. 84. I ordered Petitioner to file a response by October 26, 2022. Non-PDF Order, docketed Oct. 13, 2022.

Instead of filing a response, Petitioner filed a motion to voluntarily dismiss her claim on October 24, 2022. ECF No. 85. Petitioner indicated that she has "reviewed her options moving forward with her claim and wishes to file her case in the pending [litigation] directly against [the vaccine manufacturer]." *Id.* In light of Petitioner's motion, Respondent filed a motion to withdraw his motion to dismiss on October 25, 2022. ECF No. 86.

To receive compensation under the Program, Petitioner must prove either (1) that she suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to the vaccination, or (2) that she suffered an injury that was actually caused by a vaccine. See §§ 13(a)(1)(A), 11(c)(1). An examination of the record did not uncover persuasive evidence that Petitioner suffered from a "Table Injury." Further, the record does not contain persuasive evidence that Petitioner's injuries were caused-in-fact by her HPV vaccinations, as she cannot show by a preponderant standard that her POI is autoimmune in nature.

Under the Act, petitioners may not be given a Program award based solely on their claims alone. Rather, the petition must be supported by medical records or the opinion of a competent physician. § 13(a)(1). In this case, the medical record is insufficient to prove Petitioner's claim, and at this time, Petitioner has not filed sufficient supporting evidence. Therefore, this case must be dismissed for insufficient proof. The Clerk shall enter judgment accordingly.³

IT IS SO ORDERED.

s/Herbrina D. Sanders Herbrina D. Sanders Special Master

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³ Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.